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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/774,721	02/09/2004	Ralf Jockers	FRAV2003/0005USNP	9535

5487 7590 03/25/2010

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EXAMINER	
WOLLENBERGER, LOUIS V	
ART UNIT	PAPER NUMBER
1635	

NOTIFICATION DATE	DELIVERY MODE
03/25/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/774,721	JOCKERS ET AL.	
	Examiner	Art Unit	
	Louis Wollenberger	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 January 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *49-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *49-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Application/Amendment/Claims

Applicant's response filed 1/19/2010 has been considered. Rejections and/or objections not reiterated from the previous office action mailed 8/31/2009 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

Applicant's amendments to the claims filed 1/19/2010 are acknowledged. With entry of the amendment, claims 49-60 are pending and examined herein.

Claim Rejections - 35 USC § 103—withdrawn

The rejection of Claims 49-54 under 35 U.S.C. 103(a) as being unpatentable over Akerblom "Human leptin receptor-related protein" (US Patent 5,789,198) in view of

1. Bennett et al. (1999) *Biochimica Biophysica Acta* 1489:19-30;
2. Vickers et al. (2003) *J. Biol. Chem.* 278:7108-7118; and
3. Bennett et al. (US Patent 5,998,148)

is withdrawn upon further consideration and in view of Applicant's arguments, which are considered persuasive.

Claim Rejections - 35 USC § 102—maintained in part

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 50, 51, 53, and 54 remain rejected and new claims 56, 57, 59, and 60 are rejected under 35 U.S.C. 102(b) as being anticipated by Akerblom "Human leptin receptor-related protein" (US Patent 5,789,198).

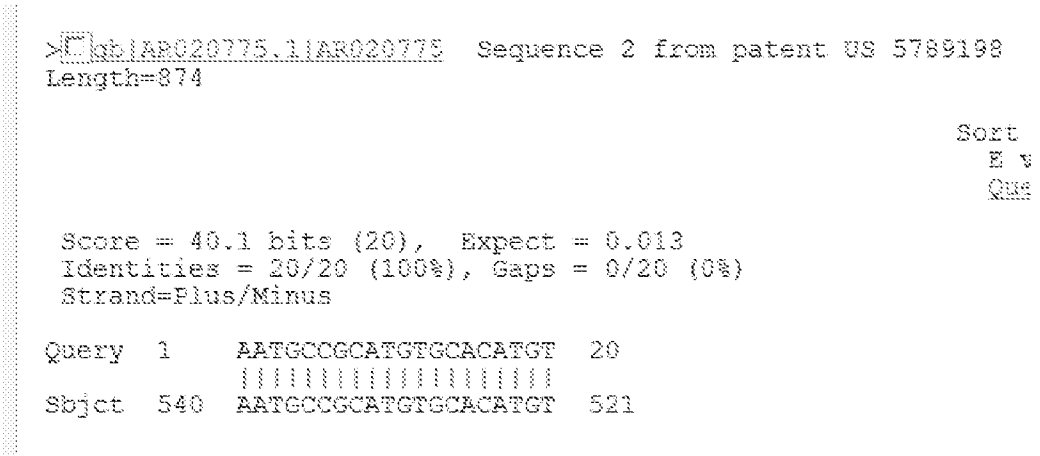
The claims are drawn to vectors "incorporating" SEQ ID NO:2 and to cells and compositions thereof containing said vector and cells. It is unclear whether the term "incorporating" includes or specifically excludes vectors containing longer antisense sequences that contain SEQ ID NO:2. See MPEP 2111.03. Accordingly, in this regard Akerblom et al. remains pertinent, as previously set forth and reiterated below.

Akerblom et al. disclosed the sense and antisense strands corresponding to a leptin receptor-related gene sequence (SEQ ID NO:2) that contains a nucleotide sequence that is 100% complementary to the instantly recited antisense oligonucleotide, SEQ ID NO:2 (see alignment below; and see cols. 2, 3 (lines 1-10), 18, and 25 (beginning at line 65)). Akerblom et al. further disclosed antisense oligonucleotides complementary to the leptin receptor-related gene sequence for inhibiting the expression of naturally occurring LRRP in cells in vitro and in vivo (cols. 2, 3 (lines 1-10), 18, and 25 (beginning at line 65)). At column 25, Akerblom et al. state the LRRP-encoding sequence, or any part thereof, is used to inhibit the expression of LRRP, reasonably implying that full or nearly full length antisense sequences may be used. In the next sentence, Akerblom et al. state "Although use of antisense oligonucleotides, comprising about 20 base-pairs, is specifically described, essentially the same procedure is used with larger cDNA fragments," again reasonably implying that long and possibly full length antisense sequences may be used. One of skill would instantly envision all such sequences based on the disclosure of the target gene, identified therein as SEQ ID NO:2 (LRRP). Such sequences would necessarily

"comprise" instant SEQ ID NO:2. (Akerblom does not disclose or suggest an antisense oligonucleotide "consisting of" instant SEQ ID NO:2).

At column 18, lines 55-65, Akerblom disclosed vectors that incorporate LRRP-specific antisense sequences for introduction into cells. Also disclosed are pharmaceutical compositions which would reasonably be used with any of the nucleic acid sequences, vectors, and cells disclosed therein (cols. 19-22).

Accordingly, Akerblom described antisense sequences, vectors, and host cells compounds and compositions within the scope of the instant claims.



>gb|AR020775.1|AR020775 Sequence 2 from patent US 5789198
Length=874

Sort
E v
Que

Score = 40.1 bits (20), Expect = 0.013
Identities = 20/20 (100%), Gaps = 0/20 (0%)
Strand=Plus/Minus

Query 1 AATGCCGCATGTGCACATGT 20
||||||||||||||||||||
Sbjct 540 AATGCCGCATGTGCACATGT 521

Claim Rejections - 35 USC § 102—new

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 49, 52, 55, and 58 are rejected under 35 U.S.C. 102(e) as being anticipated by Mounts (US Patent Application Publication 2005/0118625), entitled "Nucleic acid arrays for detecting gene expression associated with human osteoarthritis and human proteases."

To the extent it is supported by US Provisional Application 60/507511, filed 10/2/2003, Mounts represents an intervening prior art reference, having a filing date before that of the actual U.S. filing date of the instant application, 10/774721, but after those of the domestic and foreign priority documents (60/461005 and France 0301543) to which benefit is claimed. However, at present Applicant cannot rely upon the domestic or foreign priority papers (60/461005 and France 0301543) to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55 and 37 CFR 1.78. See MPEP § 201.15 and 608.01, which states If a provisional application is filed in a language other than English, an English translation of the non-English language provisional application and a statement that the translation is accurate must be submitted if benefit of the provisional application is claimed in a later-filed nonprovisional application (see 37 CFR 1.78(a)(5)).

Accordingly, because an earlier date of invention cannot be established with certainty based on the earlier filed foreign language applications, and in view of Applicant's amendment to the claims, limiting the oligonucleotide to not more than 50 nts, a search of the prior art with regard to sequences of not more than 50 nts containing SEQ ID NO:2 finds Mounts, which is considered to anticipate the claimed invention as follows.

Mounts disclosed nucleic acid arrays comprising a plurality of nucleic acid probes for the detection and quantitation of human protease and osteoarthritis genes. It is said that the probes used in such arrays can hybridize to the tiling sequences "selected from Attachment C, or the

complement thereof." (Abstract and Summary of Invention). Several 25-nt nucleic acids (ie., probes) are disclosed therein as part of the disclosure. Given that the arrays are said to be designed to detect a tiling sequence or its complement, Mounts reasonably also disclosed the 25-nt complement of each probe. As shown by the alignment below, one of the disclosed 25-nt nucleic acids, SEQ ID NO:30719 (185537 in 60/507511), contains the complete complement of instant SEQ ID NO:2. In view of the disclosure, one of skill would have instantly envisioned the complement of this probe, which would necessarily contain SEQ ID NO:2 and would necessarily also possess all properties inherent to SEQ ID NO:2. See MPEP 2112. The disclosure is supported by Provisional Application 60/507511, filed 10/2/2003. See alignment below. Compositions comprising these probes would be indistinguishable from those now claimed.

Accordingly, Mounts disclosed a nucleic acid sequence of 50 nts or less containing SEQ ID NO:2 within the scope of what is now claimed.

```
RESULT 3
US-10-956-157-301719/c
; Sequence 301719, Application US/10956157
; GENERAL INFORMATION:
;  APPLICANT: Wyeth
;  APPLICANT:  Mounts, William
;  TITLE OF INVENTION: NUCLEIC ACID ARRAYS FOR DETECTING GENE EXPRESSION ASSOCIATED WITH
;  TITLE OF INVENTION:  HUMAN OSTEOARTHRITIS AND HUMAN PROTEASES
;  FILE REFERENCE: 031896-043000 (AM 101081)
;  CURRENT APPLICATION NUMBER: US/10/956,157
;  CURRENT FILING DATE:  2004-10-04
;  NUMBER OF SEQ ID NOS: 319805
;  SOFTWARE: PatentIn version 3.2
; SEQ ID NO 301719
;   LENGTH: 25
;   TYPE: DNA
;   ORGANISM: Probe Sequence
US-10-956-157-301719

  Query Match             100.0%;  Score 20;  DB 59;  Length 25;
  Best Local Similarity   100.0%;
  Matches   20;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps    0;

Qy          1 AATGCCGCATGTGCACATGT 20
              ||||||||||||||||||||
Db         21 AATGCCGCATGTGCACATGT 2

RESULT 5
US-60-507-511-185537/c
; Sequence 185537, Application US/60507511
; GENERAL INFORMATION:
;  APPLICANT: Wyeth
;  APPLICANT:  Mounts, William M
;  TITLE OF INVENTION: NUCLEIC ACID ARRAYS FOR DETECTING GENE EXPRESSION ASSOCIATED WITH
;  TITLE OF INVENTION:  HUMAN OSTEOARTHRITIS AND HUMAN PROTEASES
;  FILE REFERENCE: AM 101081
;  CURRENT APPLICATION NUMBER: US/60/507,511
;  CURRENT FILING DATE:  2003-10-02
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;  NUMBER OF SEQ ID NOS: 203623
;  SOFTWARE: PatentIn version 3.2
; SEQ ID NO 185537
;   LENGTH: 25
;   TYPE: DNA
;   ORGANISM: Homo sapiens
US-60-507-511-185537

  Query Match            100.0%;  Score 20;  DB 100;  Length 25;
  Best Local Similarity   100.0%;
  Matches   20;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps    0;

Qy          1 AATGCCGCATGTGCACATGT 20
              ||||||||||||||||||||
Db         21 AATGCCGCATGTGCACATGT 2
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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 50, 51, 53, 54, 56, 57, 59, and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mounts as applied to claims 49, 52, 55, and 58 above, and further in view of US Patent 6,010,852 to Hillman et al.

Mounts is relied on for the reasons given above.

Mounts does not teach vectors encoding probes.

However, the use of recombinant bacterial expression vectors for expressing and producing gene fragments and complements thereof for use as probes was well established in the prior art. For example, Hillman et al. had taught at column 15, line 35, that, with regard to the polynucleotide discussed therein, HPAS, the sequences encoding HPAS, or any portions thereof may be cloned into a vector for the production of an mRNA probe. Such vectors are known in the art. It would have been obvious to those skilled in the art that any gene fragment or complement thereof could be recombinantly expressed for purposes of preparing suitable quantities of the probe for use in any detection technique. Implicit to such recombinant techniques is the transformation of bacterial cells. Accordingly probe-encoding vectors, cells, and compositions, were reasonably suggested by the prior art. It would therefore have been obvious to make vectors expressing any of the probes or complements of such probes disclosed by Mounts, including that specifically described above containing instant SEQ ID NO:2.

Response to Applicants' Arguments

Applicants' arguments presented on 1/19/2010 not specifically addressed above are considered to be moot in view of Applicants' amendments to the claims and in view of the new rejections stated herein, above.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louis Wollenberger whose telephone number is (571)272-8144. The examiner can normally be reached on M-F, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fereydoun Sajjadi can be reached on 571-272-3311. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Louis Wollenberger/
Primary Examiner, Art Unit 1635
March 17, 2010